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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,291	11/28/2006	Pascale Gaillard	GAILLARD2	6383
1444 7590 08/20/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER BALASUBRAMANIAN, VENKATARAMAN	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			08/20/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/571,291

**Applicant(s)**

GAILLARD ET AL.

**Examiner**/Venkataraman  
Balasubramanian/**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, which included amendment to claims 12 and 14, filed on 7/20/2009 has been entered. Claims 1-20 are pending. In view of applicants' response, the 112 second paragraph rejection, the 102(b) rejections and double patenting rejections made in the previous office action have obviated. However, the following rejections made in the previous office action are maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halazy et al., WO 01/47920 in view of Bennett et al., Current Opinion in Pharmacology 2003, 3:420-425.

Halazy et al., teaches several benzazole compounds useful for treating disorder of immune system cancer, which include instant compounds. See page 9, formula I and note definition of the X, G, L, R<sup>1</sup>, and R<sup>2</sup>. Note when X is S, G= pyrimidinyl with L substituents, with given definition of other variable choices, the compounds taught by Halazy et al., include instant compounds. See pages 9-24 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 28-54, for examples of compounds made. Although Halazy et al. teaches several benzothiazole compounds, Halazy et al., does not exemplify all the compounds of genus of compound of formula I shown in page 9, wherein X=S. But Halazy et al., teaches equivalency of alternate choices of all variables including X, with

the compounds taught in pages 9-55 with those generically claimed in page 9.

Currently amended claims 1-10,13 and 15-20 related to method of use different from those taught by Halazy et al. However, Halazy et al., teaches such benzothiazoles are useful in inhibiting JNKs and JNKs are known at the time of instant invention to be implicated in metabolic disorder mediated by insulin resistance or hyperglycemia such as diabetes type II, inadequate glucose tolerance and obesity.

For example, Bennett et al., teaches JNK inhibitors to be useful in treating insulin resistance, diabetes and obesity.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made based on to combined the teaching of Halazy and Bennett to make various compounds of formula I as permitted by the reference using teachings of Halazy , and expect resulting compounds to possess the uses taught by the combined art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action. Applicants' traversal to overcome this rejection is not persuasive. First of all, the compounds taught by Halazy are same as that of instant claims. Instant specification on page 2 clearly acknowledges this. The compounds of Halazy are JNK inhibitors. Thus, administering the genus of compounds Halazy that is instant genus of compounds would inhibit JNK. Whatever negative attributes applicants offer for method of use of compounds of Halazy would be equally applicable to instant compounds.

Bennett et al., clearly teaches JNK inhibitors to be useful in treating insulin resistance, diabetes and obesity as seen pages 420-422. Instant claims recite the

same. Applicants argued, pointing page that while instant compounds decreases insulin and glucose, Bennett did teaches lowering of plasma glucose but not plasma insulin. This is not correct. Contrary to applicants' urging, the Figure 2 shown in page 422 of Bennett clearly shows lowering of plasma glucose and insulin. And it is also improper comparison as applicants have measured plasma glucose level and plasma insulin level after 4 hr as pointed by applicants( see page 29, lines 18-21).

For reasons stated above this rejection is proper and is maintained.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaillard et al., WO 03/091249 in view of Bennett et al., Current Opinion in Pharmacology 2003, 3:420-425.

Gaillard et al., teaches several benzothiazole compounds useful for treating ischemic disorders, which include instant compounds. See page 3, formula A and note definition of the X, G, R<sup>1</sup>, and R<sup>2</sup>. Note when X is S, G= pyrimidinyl with substituents, with given definition of other variable choices, the compounds taught by Gaillard et al., include instant compounds. See pages 3-17 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 20-29, for examples of compounds made.

Although Gaillard et al. teaches several benzothiazole compounds, Gaillard et al., does not exemplify all the compounds of genus of compound of formula A shown in page 3, wherein X=S. But Gaillard et al., teaches equivalency of alternate choices of all variables with the compounds taught in pages 20-29 with those generically claimed in page 3. Thus, it would have been obvious to one having ordinary skill in the art at the

time of the invention was made to make various compounds of formula A as permitted by the reference using teachings of Gaillard et al., and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Currently amended claims 1-10,13 and 15-20 related to method of use different from those taught by Gaillard et al. However, Gaillard et al., teaches such benzothiazoles are useful in inhibiting JNKs and JNKs are known at the time of instant invention to be implicated in metabolic disorder mediated by insulin resistance or hyperglycemia such as diabetes type II, inadequate glucose tolerance and obesity.

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Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made based on to combined the teaching of Halazy and Bennett to make various compounds of formula I as permitted by the reference using teachings of Gaillard, and expect resulting compounds to possess the uses taught by the combined art in view of the equivalency teaching outline above.

This rejection is same as made in the previous office action. Applicants' traversal to overcome this rejection is not persuasive. First of all, the compounds taught by Halazy are same as that of instant claims and they are JNK inhibitors. Instant specification on page 2 clearly acknowledges this. The compounds of Gaillard are JNK inhibitors. Thus, administering the genus of compounds Gaillard that is instant genus of compounds would inhibit JNK. Whatever negative attributes applicants offer for method of use of compounds of Gaillard would be equally applicable to instant compounds.

Bennett et al., clearly teaches JNK inhibitors to be useful in treating insulin resistance, diabetes and obesity as seen pages 420-422. Instant claims recite the same. Applicants argued, pointing page that while instant compounds decreases insulin and glucose, Bennett did teaches lowering of plasma glucose but not plasma insulin. This is not correct. Contrary to applicants' urging, the Figure 2 shown in page 422 of Bennett clearly shows lowering of plasma glucose and insulin. And it is also improper comparison as applicants have measured plasma glucose level and plasma insulin level after 4 hr as pointed by applicants( see page 29, lines 18-21).

For reasons stated above this rejection is proper and s maintained.

### **Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For



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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624